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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Akira NAKAGAWARA et al

U.S. Appln. 10/582,508

Filed: June 9, 2006

Confirmation No. 3921

Attorney Docket No.: 7388/88180

Customer No.: 42798

For: METHOD OF DETERMINING CLINICAL SEVERITY OF FALS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir:

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO/SB/08 are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form PTO/SB/08, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form PTO/SB/08 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- (X) within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- after (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
 - () the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

- () the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- after the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- after the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and within thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- (X) Copies of the references listed on the enclosed Form SB/08 are enclosed herewith. Copies of any U.S. Patents and any U.S. Patent Application Publications are <u>not</u> enclosed.
- () A copy of the International Search Report is enclosed herewith.
- () A copy of the Supplementary European Search Report is enclosed herewith.

Information Disclosure Statement Application No. 10/582,508

() The references listed on the enclosed Form PTO/SB/08 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLI	Status (check one)			
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- () The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- () The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

() The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- (X) **No fee** is owed by the applicant(s).
- () The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

- () Attached is a check in the amount of \$180.00.
- () Charge Deposit Account No. 06-1135, under Order No. , in the amount of \$0.00. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

(X) If any additional fees are owed in connection with this communication, please charge Deposit Account No. 06-1135. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

- (X) Credit Account No. 06-1135.
- () Refund

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Date: July 27, 2006

Kendrew H. Colton, Reg. No. 30,368 Michael A. Sanzo, Reg. No. 36,912

OFFICIAL CORRESPONDENCE TO Customer No. 42798

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PTO/SB/08a Substitute for Form 1449A/PTO		THE THE THE	5 / Application Number	10/582,508						
		Filing Date	June 9, 2006							
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				First Named Invento	Akira NAKAGAWARA					
			ICANT	Art Unit	Not Yet Assigned					
			()	Examiner Name	Not Yet Assigned					
Sheet 1 of 1			1	Attorney Docket	7388/88180					
NON PA	TEN	T LITERATURE	DOCUMENTS	_	•					
Examine r Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.								
		R. NAKANO et al., "Mutant SOD1 protein forms intracellular aggregates," Cell Technology, Vol. 20, No. 11, 1508-1512, 2001								
		Ryen D. FONS et al., "Substrate-specific function of the translocon-associated protein complex during translocation across the ER membrane," The Journal of Cell Biology, Vol. 160, No. 4, 2003 (529-539)								
Examiner Signature					nte onsidered					

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.